Individual Safety Report

3242515-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, tributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse.

Mfr report #: 99-0150-042 (99-1290)

UF/Dist report #:

FDA Use Only

A. Patient information

1 Patient identifier	2 Age at time of event: 21 or Date of birth: [redacted]	3 Sex	4 Weight
[redacted] In confidence		XX female ☐ male	-NI lbs -NI kgs

B. Adverse event or product problem

1 XX Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- ☐ death (mo/day/yr)
- ☐ life-threatening
- XX hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- XX other: recovered

3 Date of event (mo/day/yr): 9/91

4 Date of this report (mo/day/yr): 04/09/99

5 Describe event or problem

According to the information provided by McNeil: "Consumer report of overdose allegedly associated with the use of an Extra Strength Tylenol product. According to consumer, on an unspecified date in September, she drank "a lot of alcohol" the night befcre at a party and awoke w/a hangover. Consumer took an unspecified amount of Tylenol for 3 days for a severe headache. On the third day, consumer reports she woke w/abdominal pain, chills, sweating and vomiting (severely). Her sister took her to the ER where they gave her fresh frozen plasma. She was transported to another hospital and admitted. Reportedly, she was given many unspecified medications and was listed for a liver transplant (liver failure). While waiting for the transplant, her liver recovered. She was discharged 5 days later. According to consumer, her physicians attributed symptoms to drug overdose with concomitant alcohol ingestion. Additional information was received 3/24/99: medical record authorization form indicates unspecified Advil product also taken. Date of admission 9/91."

6 Relevant tests/laboratory data, including dates

No information provided.

DSS

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ADVERSE EVENT REPORTING SYSTEM

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/rena dysfunction, etc.)

No known conditions; concomitant alcohol use.

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BY:

Allergic to aspirin.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 Advil (R) (Ibuprofen) Tablets

#2 Extra Srength Tylenol (acetaminophen)

2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) (from/to or best estimate)
#1 unknown	#1 Duration unk.
#2 unknown	#2 3 day(s)

4 Diagnosis for use (indication)

#1 unkown

#2 accidental overdose

5 Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no XX doesn't apply

#2 XX yes ☐ no ☐ doesn't apply

6 Lot # (if known)	7 Exp. date (if known)
#1 Unknown	#1 -NA
#2 unknown	#2 -NA

8 Event reappeared after reintroduction

#1 ☐ yes ☐ no XX doesn't apply

#2 ☐ yes ☐ no XX doesn't apply

9 NDC # – for product problems only (if known)

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10 Concomitant medical products and therapy dates (exclude treatment of event)

None reported.

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device

- ☐ health professional
- ☐ lay user/patient
- ☐ other

6

model #

catalog #

serial #

lot #

other #

5 Expiration date (mo/day/yr)

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)

☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1 Name, address & phone #

McNeil Consumer Product Co.
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034- United States
215-273-7000

2 Health professional?	3 Occupation	4 Initial reporter also sent report to FDA
☐ yes XX no	-NA	☐ yes ☐ no XX unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or

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efer to guidelines for specific instructions

f a report does not constitute that medical personnel, user utor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

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FDA Use Only

F. For use by user facility/distributor–devices only

1 Check one
☐ user facility ☐ distributor

2. UF/Dist report number

3 User facility or distributor name/address

4 Contact person

5. Phone Number

6 Date user facility or distributor became aware of event (mo-day-yr)

7 Type of report
☐ initial
☐ follow-up # ___

8 Date of this report (mo-day-yr)

9 Approximate age of device

10. Event problem codes (refer to coding manual)
patient code ___ - ___ - ___
device code ___ - ___ - ___

11 Report sent to FDA?
☐ yes ___ (mo-day-yr)
☐ no

12. Location where event occurred
☐ hospital
☐ home
☐ nursing home
☐ outpatient treatment facility
☐ outpatient diagnostic facility
☐ ambulatory surgical facility
☐ other: ___ (specify)

13 Report sent to manufacturer?
☐ yes ___ (mo-day-yr)
☐ no

4 Manufacturer name/address

G. All manufacturers

1 Contact office – name/address (& mfrng site for devices)

Whitehall-Robins
Medical Department
5 Giralda Farms
Madison, NJ 07940-0871

2 Phone number
973-660-5500

3 Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☒ other

Date received by manufacturer (mo-day-yr)
04/06/99

5 (A)NDA # 18-989
IND # -NA
PLA # ___
pre-1938 ☐ yes
OTC product ☒ yes

If IND, protocol #

Type of report (check all that apply)
☐ 5-day ☒ 15-day
☐ 10-day ☐ periodic
☒ initial ☐ follow-up # ___

8 Adverse event term(s)

LIVER FAIL
OVERDOSE
CHILLS
VOMIT
PAIN ABDO
SWEAT

Mfr. report number
99-0150-042

H. Device manufacturers only

1 Type of reportable event
☐ death
☐ serious injury
☐ malfunction (see guidelines)
☐ other: ___

2. If follow-up, what type?
☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3. Device evaluated by mfr?
☐ not returned to mfr
☐ yes ☐ evaluation summary attached
☐ no (attach page to explain why not) or provide code: ___

4. Device manufacture date (mo-yr)

5 Labeled for single use?
☐ yes ☐ no

6. Evaluation codes (refer to coding manual)
method ___ - ___ - ___ - ___
results ___ - ___ - ___ - ___
conclusions ___ - ___ - ___ - ___

7 If remedial action initiated, check type
☐ recall
☐ repair
☐ replace
☐ relabeling
☐ other: ___
☐ notification
☐ inspection
☐ patient monitoring
☐ modification/adjustment

8. Usage of device
☐ initial use of device
☐ reuse
☐ unknown

9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:

10 ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

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BY:

Please do NOT return this form to either of these addresses.